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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,546	09/29/2006	Hyun-Su Bae	53768-10100	1559

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
10/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO_Mail@hro.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,546	BAE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8,9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 8-9, 11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on June 30, 2009 has been received and entered.

Currently, Claims 1, 3-6, 8-9, 11-12 are pending. Claims 1, 3-6, 8-9, 11-12 are examined on the merits.

The declarations of PURIMED CO., LTD filed June 30, 2009 has been considered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 102

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lotus Seed (March 2002, http://www.itmonline.org/arts/lotus.htm) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Lotus Seed teaches lotus seed boiled in water and simmered for 1.25 to 1.5 hours or until the beans are tender (page 1, Red Bean and Lotus Seed Soup). Soup contains extract of the ingredients in soup. Lotus seeds can be used for food and

medicine (page 1, paragraph 1; page 2, paragraph 5.) Lotus seed is also known as Nelumbinis Semen (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm). Boiling of water in 1 atmospheric pressure requires the temperature to be 100 degree Celsius.

Applicant argues that an extract is not taught.

In response to Applicant's argument, soup is an extract of the ingredients in the soup. Thus, an extract of lotus seed is taught in lotus seed soup.

Applicant argues that simmering is not boiling.

In response to Applicant's argument, simmering is still boiling, just not as turbulent. Simmering maintains the temperature at about 100 degrees Celsius because the liquids are still being maintained at about 100 degrees Celsius, which is the boiling point at 1 atmosphere.

Applicant argues that the composition did not teach a treatment for depression or pharmaceutical use.

In response to applicant's argument that treatment for depression is not taught, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102/103

Claims 1, 3-6, 8-9, 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bae et al. (KR 1020030079104 A).

The claims are drawn to Nelumbinis Semen composition comprising Nelumbinis Semen as the active ingredient, within a product-by-process claim.

Bae et al. teaches a pharmaceutical composition and health food of an extract of Nelumbinis semen for the treatment of depression (Abstract).

The cited reference teaches a composition of 1-100% ethanol or methanol, filtering and concentrating the concentrate, as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed extract Nelumbinis Semen composition since the prepared ingredient has similar aqueous extraction, concentration steps, and demonstrate the same/similar activity with respect to treating depression. Consequently, the instantly claimed lotus seed extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed Nelumbinis Semen composition is not identical to the referenced Nelumbinis Semen extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced Nelumbinis Semen composition is likely to inherently possess the same characteristics of the claimed Nelumbinis Semen composition particularly in view of the similar characteristics which

they have been shown to share. Thus, the claimed Nelumbinis Semen composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., for use as pharmaceutical and health food to treat depression) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the Nelumbinis Semen extracts within Applicant's composition differ and, if so, to what extent, from the levels within the Nelumbinis Semen disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with

evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicant argues that ethanol extraction is not the same as water extraction.

In response to Applicant's argument, ethanol is a polar solvent. Water is also a polar solvent. Polar solvents will extract polar compounds. As evidenced by Applicant's affidavits for the chromatographic data, Exhibits 3A-C, ethanol and water extraction both contain the same major peaks at about 8 and 9 minutes. Since Applicant's claim is drawn toward Nelumbinis Semen extract with peaks at 8 and 9 minutes as seen in the water extract, any extract from Nelumbinis Semen that exhibit the same peaks at 8 and 9 will have the same compounds. Because Applicant is not specifically claiming the amount of the ingredients in peaks 8 and 9, the ethanol extract anticipates the claim. Therefore, the declaration is not persuasive.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 8-9, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bae et al. (KR 1020030079104 A) in view of Liu (CN 1368022 A) and Sohn et al. (2003, Phytomedicine, 10, 165-167) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Bae et al. teaches a pharmaceutical composition and health food of an extract of Nelumbinis semen for the treatment of depression (Abstract). However, it does not teach water at 80-100 degree Celsius for 1-3 hours and refluxing.

Liu teaches lotus seed's embryonic bud is boiled with purified water and features nutritive components (Abstract). Lotus seed is also known as Nelumbinis Semen (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm). Boiling of water in 1 atmospheric pressure requires the temperature to be 100 degree Celsius.

Sohn et al. teaches seeds of N. nucifera extracted with ethanol under reflux for 3 hours and filtrate was evaporated in vacuo (PAGE 166, Plant material and preparation of ENN). N. nucifera is also known as Nelumbinis semen or lotus seed (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm).

Liu teaches lotus seed's embryonic bud is boiled with purified water and features nutritive components (Abstract). Sohn et al. teaches seeds of N. nucifera extracted with ethanol under reflux for 3 hours and filtrate was evaporated in vacuo (PAGE 166, Plant material and preparation of ENN). Thus, an artisan of ordinary skill would reasonably expect that the process of extracting Nelumbinis semen can be done with water and refluxed for 3 hours could be used as the types of extracts to treat depression taught by the references. This reasonable expectation of success would motivate the artisan to use water extraction and refluxing for extracting Nelumbinis Semen in the reference composition. Thus, using the process of boiling in water by refluxing for 1-3 hours is considered an obvious modification of the references.

The references also do not specifically teach performing the process in the time span and temperature range claimed by applicant. The process in the time span and temperature range is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the time span and temperature range to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that the method of using water is not obvious.

In response to Applicant's argument, water has been used to cook lotus seeds for many centuries. In addition, Liu teaches lotus seed's embryonic bud is boiled with purified water and features nutritive components (Abstract). Water can be used to cook the seed and there is no reason to use water exclusively for the lotus seed bud only. Thus, one can use water to cook the whole lotus seed. An artisan of ordinary skill would clearly expect that the cooking the seed bud in water taught by Liu would function successfully to cook the whole seed taught by Sohn et al. This reasonable expectation

of success would motivate the artisan to modify the method to cook lotus seed with water.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655